



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,357	09/19/2003	Kenneth W. Whitley	P-5655/1	8169

26253 7590 02/08/2007
DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	PAPER NUMBER
1744	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/666,357	WHITLEY, KENNETH W.	
	Examiner Nathan A. Bowers	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 11 December 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7,9-16 and 18-20 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7,9-16 and 18-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

- 1) Claims 1-5, 7, 9-15 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 4912048) in view of Keilman (US 4717668) and Serkes (US 4962033).

With respect to claims 1, 2, 7, 9 and 11, Smith discloses a roller bottle container for cell growth culturing comprising an elongate cylindrical wall (Figure 1:16) having a closed bottom end and a liquid opening at an opposing top end. The elongate cylindrical wall includes a plurality of longitudinally axial extending pleats (Figure 1:28) that at least partially extend from the closed end to the top end. This is disclosed in 3, lines 1-47. Additionally, Smith teaches in column 3, line 48 to column 4, line 19 that at least one circumferential rib (Figure 3:66) is provided along the cylindrical wall. The ribs intrinsically serve to structurally reinforce the wall, while performing a variety of other functions. In addition, Smith discloses that the pleats define a plurality of opposed facing internal surfaces for the formation of cell growth thereon. This is taught in column 2, lines 4-17. Figure 2 indicates that each of the pleats includes a first sidewall extending between a first end point and a first apex (Figure 4:62), and a second sidewall extending between a second end point and the first apex. The first apex is located radially further from a longitudinal center of the container than the first and second end points. The first and second sidewalls are convergently disposed relative the first apex. Furthermore, a juncture is defined between adjacent pleats with the second end point of a first pleat being connected to the first end point of a second pleat, wherein the juncture defines a second apex (Figure 4:60). Again, this is apparent from Figure 2. Smith, however, does not expressly disclose that the ribs are integrally formed with the wall.

Keilman discloses a roller bottle container for cell growth culturing comprising a plurality of circumferential ribs (Figure 1:26) extending around the bottle. Column 1, line 60 to column 2, line 3 indicates that the ribs are formed integrally with the remainder of the flexible cylindrical wall that defines the roller bottle.

Smith and Keilman are analogous art because they are from the same field of endeavor regarding roller bottles.

At the time of the invention, it would have been obvious to equip Smith's roller bottle with a series of circumferential ribs that are integrally formed to the cylindrical wall of the container. Smith hints that such an alteration is feasible by stating in column 4, lines 8-19 that although removable ribbing is preferable, it is possible to affix the ribbings to the container sidewall. Keilman states in column 3, line 55 to column 4, line 5 state that integrally formed ribbings are beneficial because they serve to increase the rigidity of the bottle, and decrease the likelihood that the bottle will collapse during use. The increased stability caused by the ribbings allows the width of sidewalls of the container to be decreased to the point where they become gas permeable. This is beneficial because it facilitates the diffusion of critical gas to and from the roller bottle without the use of additional membranes, openings, or extra design features.

Smith and Keilman still differ from the apparatus set forth in claim 1 of the instant invention because Smith and Keilman do not indicate that the rib includes an outer wall extending radially outwardly from the pleats in such a way that the rib outer wall is flush with the outermost portions of the pleats.

Serkes discloses a roller bottle that comprises a plurality of circumferential extending pleats (Figure 3) and a plurality of longitudinally axial extending ribs (Figure 5:106) integrally formed with the roller bottle wall for reinforcing purposes. This is described in column 3, lines 3-47 and column 5, lines 44-61. From Figure 2, it is apparent that the ribs (22, 24) include an outer wall extending outwardly from the pleats so that the rib outer wall is flush with the

outermost portions (40) of the first apices of the pleats. The rib outer wall does not protrude from the first apices.

Smith and Serkes are analogous art because they are from the same field of endeavor regarding roller bottles.

At the time of the invention, it would have been obvious to ensure that the integrally formed ribs proposed by Smith and Keilman are fashioned so that the rib outer wall extending radially outwardly from the pleats is flush with the outermost portions of the first apices of the pleats. As evidenced by Serkes, it is believed that this design is well known in the art, and allows for easy construction and handling. Absent a showing of criticality, it would have been evident to create ribs in Smith's apparatus in such a way that the outermost portion of the ribs are flush with the apices of the pleats.

With respect to claims 3, 4, and 18, Smith, Keilman and Serkes disclose the apparatus in claim 1. Serkes additionally indicates that it is known in the art to provide cylindrical walls that further includes at least one unpleated longitudinal section defining a drain panel. Serkes discloses in column 4, lines 4-38 a roller bottle comprising a pleated midsection (Figure 1:14) that includes a plurality of drain channels (Figure 4:22). Figure 2 illustrates one embodiment of the invention in which the cylindrical wall includes two diametrically opposed unpleated longitudinal sections (Figure 2:24 and Figure 2:22), each defining a drain panel. At the time of the invention, it would have been obvious to utilize the drain panels disclosed by Serkes in the device proposed by Smith. Serkes teaches in column 3, lines 16-47 that drain panels represent a critical feature of roller bottles in that they facilitate the removal of liquids and

cells that would otherwise remain trapped in the pleated sections during collection procedures.

Drain panels also function as beams that prevent bending, extension, and compression of the pleats during handling and incubation. It would have been obvious to ensure that the ribs disclosed by Smith and Keilman abut and are flush with the drain panel disclosed by Serkes in order to make sure that every vertical section of the roller bottle is stabilized by either a rib or a drain panel.

With respect to claim 5, Smith, Keilman and Serkes disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Smith discloses that the top neck portion of the container includes integral external screw threads for receiving an internally screw threaded cap thereon. This is taught in column 3, lines 38-47.

With respect to claims 10, 12, and 14, Smith, Keilman and Serkes disclose the apparatus set forth in claims 9 and 11 as set forth in the 35 U.S.C. 103 rejections above. Although Smith, Keilman and Serkes do not expressly disclose specific angle measurements and separation distances that define the geometry of the pleats, it would have been obvious to construct the pleats to meet the claimed limitations. Varying the geometry of the pleats to achieve the most favorable design is simply the optimization of result effective variables that could be pursued using routine experimentation. In the absence of new or unexpected results, it would have been obvious to ensure that the first and second sidewalls define an angle of 60 degrees therebetween, that the first apices of two adjacent pleats are separated by an angle of 9 degrees, and that the second apices of two adjacent pleats are separated by a distance of 0.80 cm to 0.85 cm. This

would guarantee that the cells in solution are provided with an adequate opportunity to attach to the surface of the pleated sidewall. The manipulation of the geometry of the pleated surface is simply the act of experimenting with the roller bottle's available surface area in an effort to optimize cell adhesion. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to claims 13 and 15, Smith, Keilman and Serkes disclose the apparatus in claims 9 and 11. In addition, Serkes teaches in column 4, lines 39-54 that the first and second apices are rounded. Specifically, Serkes teaches that the first apices (Figure 3:40) are rounded and is silent as to the shape of the second apices (Figure 3:42). However, Figure 3 indicates that both sets of apices are constructed with essentially the same degree of sharpness, and that both are rounded.

At the time of the invention, it would have been obvious to round off the first and second apices of the pleats disclosed by Smith and Keilman. Serkes teaches in column 4, lines 39-54 that rounded edges are easier for cells to stick to, as opposed to sharp or pointed surfaces. Since both the first and second apices are intended to facilitate cell adhesion, it would have been apparent to ensure that both sets of apices were round in shape. Serkes further points out that rounded junctures are beneficial because they are easier to form by casting and molding, and that rounded surfaces are stronger and less subject to cracking on flexing.

With respect to claims 19 and 20, Smith, Keilman and Serkes disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. Although Smith, Keilman and Serkes do not expressly disclose the number of ribs that are on the container, it would have been

obvious to construct the container so that it includes three or four ribs. Varying the number of ribs to achieve the most structurally stable design is simply the optimization of a result effective variable that could be pursued using routine experimentation. In the absence of new or unexpected results, it would have been obvious to ensure that the container included enough ribs so that it was protected against deformation, but not so many that the container would become overly rigid. This would guarantee that the roller bottle is capable of maintaining its shape during incubation and culturing procedures. Keilman, in Figure 1, depicts a roller bottle comprising six ribs, so the construction of a roller bottle with three or four ribs is certainly feasible. See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

2) Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 4912048) in view of Keilman (US 4717668) and Serkes (US 4962033) as applied to claim 5, and further in view of O'Connell (US 4763804).

Smith, Keilman and Serkes disclose the apparatus in claim 5, however do not expressly disclose that the neck portion includes a locking arrangement for holding a cap in a locked open position on the container for maintaining the container open to an environment.

O'Connell discloses a cap and a container for cell growth culturing comprising a top end with a locking arrangement (Figure 4:20) for holding a cap (Figure 4:30) in a locked open position. This is described in column 2, line 62 to column 3, line 17.

Smith, Keilman, Serkes and O'Connell are analogous art because they are from the same field of endeavor regarding the culturing of cell samples.

At the time of the invention, it would have been obvious to incorporate the locking arrangement disclosed by O'Connell in the apparatus disclosed by Smith, Keilman and Serkes. O'Connell states in column 1, lines 6-26 that it is important to include a locking arrangement in many cell growth culturing devices that causes the device to remain locked in an open position. O'Connell states that this is due to the fact that during autoclaving, containers must be open in order to permit the interior to be fully sterilized. Further, it is necessary for the container to be open during incubation to prevent an undesirable positive pressure at the interior, as well as during cooling periods to prevent unwanted negative pressures. It is also important to maintain an opened position during cell culturing in order to permit the diffusion of critical gases to and from the cells.

3) Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (US 4912048) in view of Keilman (US 4717668) and Serkes (US 4962033) as applied to claim 11, and further in view of Sugiura (US 4749092).

Smith, Keilman and Serkes disclose the apparatus in claim 11, however do not expressly disclose that the ribs include an inner wall that extends radially inwardly from the pleats, wherein the inner wall is flush with the innermost portions of the second apices of the pleats.

Sugiura discloses a container comprising a plurality of longitudinally extending pleats (Figure 1:6) that serve to strengthen the bottle against deformation. This is disclosed in column 2, lines 34-53. Figure 3 illustrates that a circumferential rib is provided which comprises an inner wall that extends radially inwardly from the pleats, and is flush with the innermost portion of the second apices of the pleats.

Smith, Keilman, Serkes and Sugiura are analogous art because they are from the same field of endeavor regarding the use of pleats and ribs to increase the strength of bottles.

At the time of the invention, it would have been obvious to supply an inner wall flush with the innermost portions of the pleats to the apparatus disclosed by Smith, Keilman and Serkes. This additional facet of the rib would compliment the existing outer wall as a mechanism to further strengthen the pleated sidewalls of the container against deformation. A rib comprising an inner sidewall could be constructed inexpensively without detracting from the functionality of the pleated cell culture bottle.

Response to Arguments

Applicant's arguments filed 11 December 2006 have been fully considered but they are not persuasive.

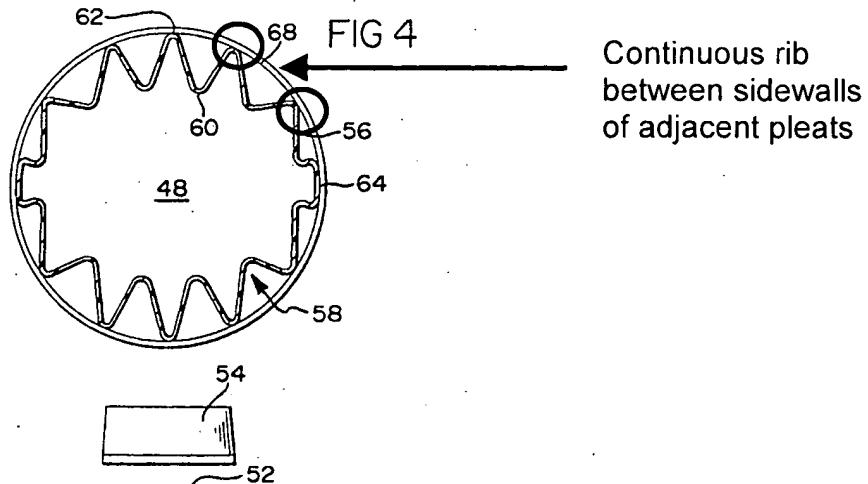
Applicant's principle arguments are

(a) The subject invention, as set forth in amended claim 1, provides for a pleated wall which is not interrupted, but has a rib superimposed thereon for additional rigidity. There is no disclosure or suggestion in Smith to provide a rib continuously between the sidewalls of each of the pleats. Serkes provides no disclosure or motivation to have any ribs extend continuously between the sidewalls of the corrugations or pleats of Smith.

In response to Applicant's arguments, please consider the following comments.

Smith does provide teachings regarding the use of ribs that extend continuously between the sidewalls of the disclosed pleats. From Figure 4, it is clear that the reinforcing rib structure

of Smith extends radially outwardly from and continuously between the sidewalls of each of the pleat.



Continuous rib
between sidewalls
of adjacent pleats

The Keilman and Serkes references are merely used to show that it would have been obvious to integrally form the ribs of Smith with the sidewalls of the container in such a way that the outer walls of the ribs are flush with the outermost portions of the pleats. In making the modification suggested by Keilman and Serkes, it would have been apparent to maintain the continuous nature of the circumferential ribs taught by Smith.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


NAB


GLADYS J.P. CORCORAN
SUPERVISORY PATENT EXAMINER